Message (Digitally Signed)

From: Michael Dourson [dourson@tera.org]
Sent: 9/29/2020 2:23:46 PM
To: linda.abbott@usda.gov; Kunickis, Sheryl - OSEC [Sheryl.Kunickis@osec.usda.gov]; Brightbill, Jonathan (ENRD) [Jonathan.Brightbill@usdoj.gov]; Dunn, Alexandra [dunn.alexandra@epa.gov]; Keigwin, Richard [Keigwin.Richard@epa.gov]; Jones, Danielle Y. EOP/OMB [Danielle_Y_Jones@omb.eop.gov]; senator_jbarrasso@barrasso.senate.gov; csmith@gowanco.com; Ray McAllister [rmcallister@croplifeamerica.org]; Alternatives@cdpr.ca.gov; Jesse.Cuevas@cdpr.ca.gov; kstammen@ofbf.org; Kiersten Mitchell [kiersten_mitchell@portman.senate.gov]; fburkett@ofbf.org; Bernard Gadagbui [gadagbui@tera.org]; Pat McGinnis [mcginnis@tera.org]; Chijioke Onyema [onyema@tera.org]; John Dale Dunn MD JD [jddmdjd@web-access.net]
Subject: Re: Chlorpyrifos & EPA's Science Transparency Rule
Attachments: smime.p7s

Dear Colleagues

Please see a response to a recent article by the New York Times:
https://www.linkedin.com/pulse/epidemiology-chlorpyrifos-transparency-michael/

Cheers!

Michael

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On Jun 4, 2020, at 8:03 AM, Michael L. Dourson <dourson@tera.org> wrote:

Dear Colleagues

Below is a clearer version of our abstract regarding chlorpyrifos written by Dr. John Dunn, an emergency physician in Brownwood, Texas, and also a writer for the Heartland Institute (e.g., https://www.heartland.org/publications-resources/publications/heartland-institute-comments-to-epa-on-strengthening-transparency-in-regulatory-science).

Please feel free to send this to whomever might be interested in understanding how some research is *not* helpful in promulgating rules and regulations.

Cheers!

Michael

---If you can't explain it simply, you don't understand it well enough. Albert Einstein

A commentary on some epidemiology data for chlorpyrifos

Michael Dourson, Bernard Gadagbui, Chijioke Onyema, Patricia McGinnis

The insectide Dursban (chlorpyrifos is the chemical name) has been asserted to be toxic and the safe level (critical effect) is the point where cholinesterase (a critical nerve function enzyme) levels are impacted to any degree--a very safe margin indeed. Dursban has always been regulated according to the critical effect as the triggering level for safety.

Rauh et al. from the Columbia Center for Children's Environmental Health (CCCEH) published in 2011 a paper (supported by public grants) asserting that they had determined a much lower level than the critical effect level was necessary because their research showed a negative impact on 7 year old childrens' memory and IQ from fetal (prenatal/in utero) exposures much lower than the critical effect level currently in use.

We attempted to repeat the Rauh study as published and failed to replicate and confirm their claims. We have assiduously attempted to obtain the Rauh data sets and methods in order to repeat our efforts and be sure that data missing from the published data (Fig. 1A and 1E of the Rauh 2011 paper) might resolve the problem of failure to replicate and confirm the Rauh assertions and findings. The data is not available or will not be released by the Rauh group, an example of the problem of lack of transparency and good reason to require that all publicly financed research should be transparent with data sets available.

On May 14, 2020, at 10:36 AM, Michael Dourson <dourson@tera.org> wrote:

Dear Colleagues

Below are comments to EPA on its science transparency rule. Since we used chlorpyrifos as an example, we thought it best to share with you.

Cheers!

Michael…

... L. Dourson, Ph.D., DABT, FATS, FSRA
Director of Science

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Agency: Environmental Protection Agency (EPA)
Document Type: Rulemaking
Title: Strengthening Transparency in Regulatory Science
Document ID: EPA-HQ-OA-2018-0259-9322

Comment:
EPA's science transparency rule is reasonable for risk judgment

Dear Colleagues,

We, fully support, with one enhancement, EPA's science transparency rule announced at https://www.epa.gov/osa/strengthening-transparency-regulatory-science. The principal reason for our support is that any one study, especially one with significant societal impact, should be sufficiently robust so that it can be replicated, if needed, with similar/same results, because positive findings can occur, on average, in one out of every 20 studies due to chance (Randall and Welser, 2018). If a study cannot be replicated, when needed, and many of them cannot for a variety of reasons, then the study results need to be consistent with scientific knowledge of the chemical/agent, and the pattern of available data. In addition, the results need to be shared in an appropriate manner so that scientists within federal agencies charged with the protection of public health can peer review and verify the results, or explain discrepancies with other studies or findings.
A case in point is the publication of human studies on chlorpyrifos that show an unexpected effect (Rauh et al., 2011). The findings have not been replicated nor are they consistent with other studies that point to changes in a blood enzyme (cholinesterase) as the first adverse effect at higher exposures. EPA scientists requested the underlying data from the authors in order to confirm the adverse effect purported to occur at lower doses. The authors demurred citing confidentiality concerns, despite EPA policies and procedures long in place to handle confidential information. Thus, EPA chose not to use the results from this human study in their regulatory decision-making.

A recent publication confirms this EPA decision. Since the underlying data were not made available, Dourson et al. (2020) extracted data from the published figures of Rauh et al. (2011) and found a significant portion of data apparently excluded. Moreover, the reported associations of chlorpyrifos levels with health effects could not be fully replicated. Dourson et al. (2020) also requested access to the data from Raul et al. so that confirmation could be attempted, but received no response. The apparent incomplete data, inconsistency with cholinergic responses as the first adverse effect in other research, and lack of communication, including on-again-off again correspondence between the journal editor and Professor Rauh regarding an invited letter to the editor, raise concerns about data transparency by the authors.

From our perspective, EPA's decision not to use such studies, suitably redacted to protect confidential information, is appropriate. The public's interest is best served when science is replicable and consistent with other information. When studies cannot be replicated or when such studies are not consistent with other information, using such studies then depends on having access to the underlying data for independent analysis. When the underlying data are not provided, it is difficult to use such studies to make a credible risk judgment for human health, much less national rulemaking.

In short, the public is often worried about chemical exposure, as they should be when such exposure exceeds a

safety level. However, protection of the public is best served by trusting experts dedicated to public health and sharing of data and findings, not by withholding scientific data or avoiding rigorous discussions or independent analysis.

We encourage EPA to proceed with this rulemaking and to expand its procedures for protecting confidential business information to include suitably redacted, personal medical information.

Sincerely,

Michael L. Dourson, Ph.D., DABT, FATS, FSRA
Bernard K. Gadagbui, MS, PhD, DABT, ERT
Patricia M. McGinnis, PhD, DABT
Toxicology Excellence for Risk Assessment (TERA)
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References

Dourson, M., B. Gadagbui, C. Onyema, and P. McGinnis. 2020. A Commentary on Some Epidemiology Data for Chlorpyrifos. Regulatory Toxicology and Pharmacology. Volume 113, June 2020, 104616. [For a short version see: [For a short version see: https://www.pubfacts.com/detail/visualize/32119975]

Randall, D. and C. Welser. 2018. The Irreproducibility Crisis of Modern Science: Causes, Consequences, and the Road to Reform. National Association of Scholars. ISBN: 978-0-9986635-5-5, April 17.

Rauh, V., S. Arunajadai, M. Horton, F. Perera, L. Hoepner, D.B. Barr, and R. Whyatt. 2011. Seven-Year Neurodevelopmental Scores and Prenatal Exposure to Chlorpyrifos, a Common Agricultural Pesticide, Environ Health Perspectives. 119(8): 1196-1201. doi:10.1289/ehp.1003160.

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